

### **In Vitro Diagnostic Medical Devices Harmonized Standards**

*Note: This list of In Vitro Diagnostic Medical Devices Harmonized Standards is from the  
Web Site: <http://www.newapproach.org>*

<b>European Standards Bodies</b>	<b>Standard reference</b>	<b>Titles</b>	<b>Ratification date</b>	<b>Publication OJ</b>
CEN	EN 928	In vitro diagnostic systems – Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices	1995	C 227 of 1999-08-10
CEN	EN 1658	Requirements for marking of in vitro diagnostic instruments	1996	C 227 of 1999-08-10
CEN	EN 12286	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures	1998	C 227 of 1999-08-10
CEN	EN 12287	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials	1999	C 293 of 2000-10-14
CEN	EN 12322	In vitro diagnostic medical devices – Culture media for microbiology - Performance criteria for culture media	1999	C 288 of 1999-10-09